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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,845	10/23/2001	Shlomo Ben-Haim	298858-00056	1690

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EXAMINER
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OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3766

NOTIFICATION DATE	DELIVERY MODE
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02/04/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipmail@eckertseamans.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/039,845	<b>Applicant(s)</b> BEN-HAIM ET AL.	
	<b>Examiner</b> FRANCES P. OROPEZA	<b>Art Unit</b> 3766	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11/2/09 (Amendment).
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5, 10-21, 23, 25 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5, 10-21, 23, 25 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Response*

1. The Applicant amended at least the independent claim 5 in the response file 11/2/09, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 5, 10-21, 23, 25 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner appreciates the Applicant's effort to identify support in the specification for the new limitations found in claims 5 and 28. Based on a review of passages in the specification cited by the Applicant, the Examiner finds the following limitations in quotations are not supported by the specification as originally filed, and hence are deemed new matter:

In claim 5:

- a memory "which stores a desired activation profile of a non-arrhythmic heart",
- a controller "which estimates a non-arrhythmic current profile based on said

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physiological activity and determines an electrification pattern according to said non-arrhythmic current profile and said desired activation profile”

- a stimulus “according to said electrification pattern”, and
- a first “non-excitatory” stimulus.

In claim 28:

- “said desired activation profile define synchronization of the contractions of the left and right ventricles”.

New matter can not be entered at this point in the prosecution. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. Claims 5, 10-21, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Zipes (U.S. Patent No. 4,384,585) (cited in the last Office Action).

Zipes discloses a heart control apparatus that can be programmed, the program to run the device accepted to be stored in memory within the device (column 2, line 21), the device comprising a sensor that can detect cardiac activity (column 3, line 63), the device further comprising generating non-excitatory stimulus in the area of the heart that is involved in the genesis and maintenance of tachyarrhythmias, where the first stimulation has a first effect on the first area of the heart and the second stimulation has a second effect on the second area of the heart, such that the relationship between the areas stimulated modifies the relationship between the contractions in these two areas of the heart. The areas of the heart treated can be the atria or ventricles. When the ventricles are determined to originate and maintain the tachyarrhythmia, the ventricles are

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simultaneously controlled and stimulated for a few beats every certain period of time, to increase the flow from one ventricle and decrease the flow from the other ventricle (abstract; columnn1, lines 31-34; column 1, line 55 – column 2, line 3; column 3, lines 12-18, 38-43; column 4, lines 6-11; column 4, line 37 – column 5, line 4).

Note the concept of non-excitatory stimulation amounts to an intended use limitation of which Zipes inherently performs or is capable of performing.

Claim 5 is an apparatus claim, and an apparatus claim is limited by structure. The newly added limitation "wherein said first effect is not prevention or amelioration of arrhythmia" does not provide for any alteration or further detail related to the structure of the apparatus, hence the newly added limitation is viewed as having a limited impact on the scope of the claim and claim 5 is rejected.

As to claims 14 and 25, the stimulation is periodically delivered in response to a detected intrinsic ventricular depolarization, hence for a patient with periodic intrinsic activity, the device will control the heart for a few beats, every certain period of time using non-excitatory stimuli.

As to claim 15, 19 and 20, the stimulation is accepted to modify the contractility hence it is accepted to be excitatory .

As to claims 16, 17 and 21, the system, including circuitry, is accepted to impact non-arrhythmic tissue during period when no arrhythmia activity is present.

As to claims 18 and 23, the treatment impacts arrhythmias, cardiac rhythms accepted to have low cardiac output, hence the stimuli are accepted to increase cardiac output.

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5. Claims 5, 10, 11, 13-21, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Prystowsky et al. (U.S. Patent No. 4,554,922) (cited in the last Office Action).

Prystowsky et al. disclose a heart control apparatus generating non-excitatory stimulus in heart tissue during the refractory period of the cardiac cycle, where the first stimulation has a first effect on the first area of the heart and the second stimulation has a second effect on the second area of the heart, such that the relationship between the contractions in these two areas of the heart is modified. For example, when the right ventricular contraction is modified, this changed results in a modification of the relationship to the left ventricle. Single or multiple areas of the heart can be simultaneously stimulated for a few beats every certain period of time (abstract; column 1, lines 28-36; column 54 – column 2, lines 11). The heart control apparatus comprises a memory associated with the programmable stimulator (60) (column 5, line 64) and a sensor to detect the heartbeats (column 6, lines 1-2).

Note the concept of non-excitatory stimulation amounts to an intended use limitation of which Prystowsky et al. inherently performs or is capable of performing.

Claim 5 is an apparatus claim, and an apparatus claim is limited by structure. The newly added limitation "wherein said first effect is not prevention or amelioration of arrhythmia" does not provide for any alteration or further detail related to the structure of the apparatus, hence the newly added limitation is viewed as having a limited impact on the scope of the claim and claim 5 is rejected.

As to claims 14 and 25, the stimulation is selectively delivered to inhibit cardiac arrhythmias, hence for a patient with periodic arrhythmias, the device will control the heart

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for a few beats, every certain period of time, every certain period of time using excitatory stimuli.

As to claim 15, 19, 20 and 24, the stimulation is accepted to be excitatory and modify the contractility, either increasing or decreasing the contractility.

As to claims 16, 17 and 21, the system, including circuitry, is accepted to impact non-arrhythmic tissue during period when no arrhythmia activity is present.

As to claims 18 and 23, the treatment impacts arrhythmias, cardiac rhythms accepted to have low cardiac output, hence the stimuli are accepted to increase cardiac output and be excitatory in nature.

### ***Claim Rejections - 35 USC § 103***

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prystowsky et al. (U.S. Patent No. 4,554,922) in view of Zipes (U.S. Patent No. 4,384,585).

As discussed in paragraph 7 of this action, Prystowsky et al. disclose the claimed invention except for the heart control apparatus controlling both ventricles.

Zipes teaches synchronized cardioverting using a lead configuration that delivers a electrical stimulation to both ventricles of the heart for the purpose of treating the point of origin and maintenance of tachycardia. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a lead configuration that delivers a charge to both ventricles of the heart in the Prystowsky et al. in order to use a proven treatment that includes both ventricular areas in the heart, so a more comprehensive treatment can be applied to the cardiac tissue of the patient, so the

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tachycardia can be successfully treated, and the development of fibrillation can be avoided (column 1, lines 31-34, 61-66; column 3, lines 12-18, 24-31; column 4, lines 6-11).

### *Specification*

7. The amendment filed 11/2/09 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is shown below in quotations:

In claim 5:

- a memory “which stores a desired activation profile of a non-arrhythmic heart”,
- a controller “which estimates a non-arrhythmic current profile based on said physiological activity and determines an electrification pattern according to said non-arrhythmic current profile and said desired activation profile”
- a stimulus “according to said electrification pattern”, and
- a first “non-excitatory” stimulus.

In claim 28:

- “said desired activation profile define synchronization of the contractions of the left and right ventricles”.

Applicant is required to cancel the new matter in the reply to this Office Action.



*Statutory Basis*

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

*Conclusion*

**THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).**

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. Fran's schedule typically is Monday and Tuesday 9AM-7PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. Carl's schedule typically is Monday, Wednesday, Friday 9AM-5 PM EST; Tuesday, Thursday 9AM-3PM and 9PM-11PM EST. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Frances P. Oropeza/  
Patent Examiner, Art Unit 3766  
January 30, 2010

/Carl H. Layno/

Supervisory Patent Examiner, Art Unit 3766